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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,291	07/28/2003	Guangqiang Jiang	A329-USA	6474

24677 7590 09/13/2007

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EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
09/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,291	JIANG ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/28/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/28/03, 9/22/03, 8/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukuma et al. (US Patent no. 4,587,225).

In regard to claim 1, Tsukuma et al. disclose a method for producing a long-lived, stabilized tetragonal zirconia polycrystal ceramic, col 1 lines 6-16 and col 2 lines 3-14, comprising the step of hot isostatic pressing said ceramic at a controlled temperature, at a controlled pressure, col 2 lines 14-27 and col 8 line 50 – col 9 line 21, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, col 3 lines 60-62, to substantially eliminate open porosity and to increase bulk density to about 100%, col 2 lines 10-12 of theoretical, thereby substantially eliminating low-temperature degradation of said polycrystal ceramic.

In regard to claims 2 and 3, the tetragonal zirconia polycrystal is stabilized with between 1.5 to 5 mol percent Yttria, col 8 lines 50-53.

In regard to claim 6, the hot isostatic pressing is controlled at a temperature between 1300^0 C to 1600^0 C, col 8 lines 61-65.

In regard to claim 7, the hot isostatic pressing is controlled at a pressure between 50 to 200 MPa, col 8 lines 61-66.

In regard to claims 8 and 9, the hot isostatic pressing is controlled at an atmosphere in argon, col 8 lines 61-66.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4, 5 and 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukuma et al. (US Patent no. 4,587,225) in view of Jiang et al. ("Accelerated Life Testing of Y-TZP Ceramic"; Proceedings of the 6th Annual Grodins Graduate Research Symposium, Biomedical Engineering Department, USC, Los Angeles, CA March 23, 2002, pages 70-71).

In regard to claim 10, Tsukuma et al. disclose a method for producing a long-lived, stabilized tetragonal zirconia polycrystal ceramic, col 1 lines 6-16 and col 2 lines 3-14, comprising the step of hot isostatic pressing said ceramic at a controlled temperature, at a controlled pressure, col 2 lines 14-27 and col 8 line 50 – col 9 line 21, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, col 3 lines 60-62, to substantially eliminate open porosity and to increase bulk density to about 100%, col 2 lines 10-12 of theoretical, thereby substantially eliminating low-temperature degradation of said polycrystal ceramic. However, Tsukuma et al. does not teach the use of the ceramic material to be used as a housing for an

implantable medical device. Jiang et al. teach that Yttria stabilized tetragonal zirconia polycrystal is an implantable structural ceramic material (abstract), and is a material that can be used for the BION microstimulator (see introduction, paragraph 1). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ceramic produced by the method of Tsukuma et al. to produce a microstimulator housing since Jiang et al. provide the teaching that the ceramic of Tsukuma et al. is preferable for microstimulator housings because it combines high strength and moderate fracture toughness.

In regard to claims 4, 5, 13, and 14, Tsukuma et al. substantially describe the invention as claimed except for forming the ceramic into implantable hollow tubes. Jiang et al. teach that the ceramic is pressed into tubes, (see methods, paragraph 1). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the ceramic into tubes since Jiang et al. teach that the ceramic is used housing for the BION microstimulator which is well known in the art to micro-tubule shaped.

Further in regard to claims 5 and 14, Tsukuma et al. in view of Jiang et al. disclose the claimed invention with the exception of specific dimensions for the formed implantable tube. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 100 mm or less for length, 10 mm or less for diameter, and 2 mm or less for wall thickness of the claimed tube since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the

claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). It is also well known in the art that the dimensions of the BION microstimulator, which is the embodiment of the Jiang et al., are of the millimeter scale or smaller.

In regard to claims 11 and 12, the tetragonal zirconia polycrystal is stabilized with between 1.5 to 5 mol percent Yttria, col 8 lines 50-53.

In regard to claim 15, the hot isostatic pressing is controlled at a temperature between 1300^0 C to 1600^0 C, col 8 lines 61-65.

In regard to claim 16, the hot isostatic pressing is controlled at a pressure between 50 to 200 MPa, col 8 lines 61-66.

In regard to claims 17 and 18, the hot isostatic pressing is controlled at an atmosphere in argon, col 8 lines 61-66.

5. Claims 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukuma et al. (US Patent no. 4,587,225) in view of Whitehurst et al. (US Patent no. 6,735,475).

In regard to claim 19, Tsukuma et al. disclose a method for producing a long-lived, stabilized tetragonal zirconia polycrystal ceramic, col 1 lines 6-16 and col 2 lines 3-14, comprising the step of hot isostatic pressing said ceramic at a controlled temperature, at a controlled pressure, col 2 lines 14-27 and col 8 line 50 – col 9 line 21, and in a controlled atmosphere to achieve an average grain size of less than about 0.5

micron, col 3 lines 60-62, to substantially eliminate open porosity and to increase bulk density to about 100%, col 2 lines 10-12 of theoretical, thereby substantially eliminating low-temperature degradation of said polycrystal ceramic. However, Tsukuma et al. does not teach the use of the ceramic material to be used as a housing for an implantable medical device. Whitehurst et al. disclose a microstimulator, known as the BION, col 8 lines 31-34, with a housing that can me fabricated from ceramic, col 16 lines 1-3, with dimensions of 3-5 mm or less in diameter, 20-35 mm or less in length, col 15 lines 50-53, wherein the microstimulator hosuing is a thin elongated cylinder, col 15 lines 56-59. The microstimulator may be inserted into a patient via a hypodermic syringe, col 15 lines 60-62. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ceramic formed by Tsukuma et al. as a microstimulator housing since Whitehurst et al. teach that microstimulator housings can be made from ceramic.

In regard to claim 20, the hot isostatic pressing is controlled at a pressure between 50 to 200 MPa, col 8 lines 61-66.

In regard to claim 21, the hot isostatic pressing is controlled at a temperature between 1300^0 C to 1600^0 C, col 8 lines 61-65.

In regard to claim 22, the hot isostatic pressing is controlled at an atmosphere in argon, col 8 lines 61-66.

In regard to claim 23, Tsukuma et al. disclose a method for producing a long-lived, stabilized tetragonal zirconia polycrystal ceramic, col 1 lines 6-16 and col 2 lines 3-14, comprising the step of hot isostatic pressing said ceramic at a controlled

temperature, at a controlled pressure, col 2 lines 14-27 and col 8 line 50 – col 9 line 21, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, col 3 lines 60-62, to substantially eliminate open porosity and to increase bulk density to about 100%, col 2 lines 10-12 of theoretical, thereby substantially eliminating low-temperature degradation of said polycrystal ceramic. The ceramic surface is also polished, col 5 line 68 – col 6 line 2. However, Tsukuma et al. does not teach the use of the ceramic material to be used as a housing for an implantable medical device. Whitehurst et al. disclose a microstimulator, known as the BION, col 8 lines 31-34, with a housing that can me fabricated from ceramic, col 16 lines 1-3, with dimensions of 3-5 mm or less in diameter, 20-35 mm or less in length, col 15 lines 50-53, wherein the microstimulator hosuing is a thin elongated cylinder, col 15 lines 56-59, wherein the ends of the microstimulator are hermetically sealed with metal ends (i.e., the electrodes 156 and 158), col 16 lines 1-11. The microstimulator may be inserted into a patient via a hypodermic syringe, col 15 lines 60-62. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ceramic formed by Tsukuma et al. as a microstimulator housing since Whitehurst et al. teach that microstimulator housings can be made from ceramic.

In regard to claim 24, the ceramic of Tsukuma et al. has a three point bending stress of at least 1700 MPa, col 3 lines 21-35.

In regard to claim 25, the hot isostatic pressing is controlled at a temperature between 1300^0 C to 1600^0 C, col 8 lines 61-65.

In regard to claim 26, the hot isostatic pressing is controlled at a pressure between 50 to 200 MPa, col 8 lines 61-66.

In regard to claim 27, the hot isostatic pressing is controlled at an atmosphere in argon, col 8 lines 61-66.

In regard to claim 28, the hot isostatic pressing is controlled at an atmosphere in argon for 30 minutes, col 8 lines 61-66.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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